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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,294	07/21/2003	Brent Vernon	130588.91426	7378

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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/624,294	Applicant(s) VERNON ET AL.	
	Examiner Cybille Delacroix-Muirheid	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-14 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 July 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/01/03</u> . | 6) <input type="checkbox"/> Other: ____. |

Detailed Action

Claims 1-14 are presented for prosecution on the merits.

Abstract

The abstract of the disclosure is objected to because the abstract is not limited to a single paragraph. Correction is required. See MPEP § 608.01(b).

Information Disclosure Statement(s)

Applicant's information disclosure statement received Dec. 1, 2003 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Claim Objection(s)

1. Claims 5, 6 are objected to because of the following informalities: in claim 5, line 1, "AAc" should be cancelled and replaced with –acrylic acid–. In claim 6, line 2, "Phenstin" should read –Phenstatin–. Appropriate correction is required.

Claim Rejection(s)—35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 4, 6, 7-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 6 recite the limitation "Phenstatin acrylate" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

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Claim 7 recites the limitation "Phenstatin acrylate" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation "the compound" in line 1. There is insufficient antecedent basis for this limitation in the claim. The Examiner respectfully suggests canceling "compound" and adding --drug delivery system--.

Claim Rejection(s)—35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-4, 6-8, 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 9934788 ('788) in view of Hatefi et al.

WO '788 discloses pharmaceutical compositions containing phenstatin. The compositions may be formulated for localized use. WO '788 additionally discloses that the compositions containing phenstatin may be used for inhibiting cancer cell growth in humans. Please see the abstract; page 21, lines 7-8; claims 3 and 5.

WO '788 does not disclose that the composition contains phenstatin chemically bound to polymer poly(N-isopropylacrylamide) (or poly(NIPAAM)); however, the Examiner refers to Hatefi et al., which teach that poly(NIPAAM) is a thermosensitive polymer which exhibits lower critical solution temperature at about 32 degrees Celsius. Hatefi et al. also teach that poly(NIPAAM) is unique with respect to the sharpness of its almost discontinuous transition thus making poly(NIPAAM) potential material for use in *in situ* setting drug delivery. Please see page 18, second column, first full paragraph.

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the pharmaceutical composition of WO '788 by binding or conjugating phenstatin with poly(NIPAAM) because Hatefi et al. suggest the use of poly(NIPAAM) for in situ delivery compositions, and based on the desirable properties of poly(NIPAAM), one of ordinary skill in the art would reasonably expect the composition containing poly(NIPAAM) to effectively deliver the phenstatin locally to the cancer cells to be treated. Such a modification would have been motivated by the

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reasonable expectation of producing a phenstatin-containing composition suitable for in situ use wherein the composition effectively delivers phenstatin to the cancer thus inhibiting the growth of cancer cells.

With respect to the concentration of phenstatin in the composition, it would have been obvious to one of ordinary skill in the art to further modify the amount of phenstatin contained in the composition such that it is present in amounts effective to inhibit cell cancer cell growth. Furthermore, concerning claims 2, 7, 8, it would have been obvious to one of ordinary skill in the art to determine the manner in which phenstatin is bound to poly(NIPAAm) such that both agents maintain their desirable properties.

Finally, concerning claim 14, since WO '788 discloses that phenstatin exhibits anti-neoplastic activity, one of ordinary skill in the art would reasonably expect phenstatin to exhibit anti-neoplastic activity against breast, prostate, lung and colon tumors. Please also see Table 3, page 8 of WO '788.

Conclusion

Claims 1-4, 6-14 are rejected.

Claim 5 is objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybill Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

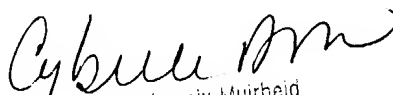
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM

September 29, 2004


Cybilie Delacroix-Muirheid
Patent Examiner Group 1600